GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:1158
ANSWERED ON:08.12.2004
EXPORT OF A NEW DRUG
Shakya Shri Raghuraj Singh

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether specific permission for every shipment of a new drug has to be taken from the Drug Controller of India even though the same drug has been exported by the same company in the past;

(b) if so, whether the Chemexcil has drawn the attention of the Government to the matter and suggested one time permission for specified period; and

(c) if so, the reaction of the Government thereto and the steps taken by the Government in the matter?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH & FAMILY WELFARE (SMT. PANABAKA LAKSHMI)

(a) to (c) As per the present norms unapproved drugs which otherwise cannot be manufactured and marketed in the country are allowed to be manufactured for export on the basis of No Objection Certificate (NOC) issued by the office of Drugs Controller General (India). Such NOC`s are issued on the basis of export orders. CHEMEXCIL has suggested for a general one-time permission for the manufacture of unapproved drugs for export purposes only. However, since, the approval granted by the State Licensing Authority for the manufacture of the said unapproved drugs is valid for a specific export order, the manufacturer is required to obtain NOC related to the said specific export order.